UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/527,216	04/21/2005	Michio Ishibashi	2005_0275A	2843

513 7590 09/04/2008

WENDEROTH, LIND & PONACK, L.L.P.
2033 K STREET N. W.
SUITE 800
WASHINGTON, DC 20006-1021

EXAMINER	
JEAN-LOUIS, SAMIRA JM	

ART UNIT	PAPER NUMBER
1617	

MAIL DATE	DELIVERY MODE
09/04/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/527,216	ISHIBASHI, MICHIO	
	Examiner	Art Unit	
	SAMIRA JEAN-LOUIS	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 May 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *16,17,21-28 and 39-44* is/are pending in the application.

4a) Of the above claim(s) *17 and 21-28* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *16 and 39-44* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

This Office Action is in response to the amendment submitted on 05/12/08 and 05/28/08. Claims 16-17, 21-28, and 39-44 are currently pending in the application, with claims 1-15, 18-20, and 29-38 having being cancelled. Accordingly, claims 16 and 39-44 are being examined on the merits herein.

Receipt of the aforementioned amended claims is acknowledged and has been entered.

Applicant's argument with respect to the fact that Examiner has mischaracterized applicant's claim has been fully considered but is not found persuasive. The claims as previously presented recited a limitation wherein "a compound" was to be tested on the on the induction of immune cells" that was not given patentable weight due to the fact that such statement is viewed as a possible step to be taken in the future. However, in view of applicant's amendment such arguments are now moot. Consequently, the rejection of claim 16 under 35 U.S.C. § 102 (b) is now withdrawn.

Applicant's contention that the prior art does not teach or suggest a method of screening comprising measuring a promoting action of a compound has been fully

acknowledged but is not found persuasive. Again, Examiner respectfully points out that applicant's arguments are directed to the amended claims. The claims as previously presented recited the limitation of a compound to be tested on the induction of particular immune cells. Given that applicant's step was directed to a possible future step, such limitation was not given patentable weight. However, in view of applicant's amendment, the rejection of claim 16 under 35 U.S.C. § 102 (b) is now withdrawn.

Applicant's argument with respect to the fact that the prior art does not teach or suggest claim 44 has been considered but is not found persuasive. Once again, Examiner would like to point out that applicant's arguments are directed to a newly presented claim. As a result, such arguments are moot. However, in view of applicant's amendment, the rejection of claim 16 under 35 U.S.C. § 102 (b) is now withdrawn.

For the foregoing reasons, the rejections of claim 16 under 102 (b) and 112, first paragraph were proper. However, in view of applicant's amendment, the aforementioned rejections are hereby withdrawn and the following modified 103 (a) Final rejection is being made.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 16 and 39-44 are rejected under 35 U.S.C. 103 (a) as being unpatentable over Ishibashi et al. (EP 12777747 A1, previously cited and submitted).

WO 01/72730 A1 is the PCT counterpart to EP 1277747 A1. WO 01/72730 A1 is prior art under U.S.C. 102 (b) as a result of its April 10, 2001 publication date. EP 1277747 A1 is prior art under U.S.C. 102 (a). Because WO 01/72730 A1 and EP 1277747 A1 appear to have identical disclosures, the European patent application is being used as a translation of WO 01/72730 A1 PCT. While any reference hereinafter to column and line numbers will be based upon the European patent application disclosure, such reference should be interpreted as referring to the corresponding disclosure of the aforementioned PCT counterpart.

Ishibashi et al. disclose an invention that relates to a screening method for compounds that selectively suppress effector macrophages involved in progressive lesions which acts through cytotoxic manner without inhibiting the function and regeneration process of the organ by macrophages involved in the regeneration process (see abstract, pg. 2, paragraph 002, pg. 4, paragraph 0018, pg. 45, paragraphs 0297-0298, and pg. 46, paragraph 0306). The aforementioned method entails

measuring suppressive action of the test compound against the induction of effector macrophages caused by contact of peripheral blood mononuclear cells with lipopolysaccharide (see pg. 6, paragraph 011). Ishibashi et al. further discloses that suppression of macrophages occur via suppressing expression and function of various chemokine receptors such as CCR2, CCR3, CCR8, β2 integrin receptors such as CD11b/CD18 (see pg. 4, lines 37-41). Taken together, this suggests that Ishibashi necessarily teach a method of screening which entail the use of compounds involved in regulating the actions of CD11 b cells. Additionally, Ishibashi et al. teach that the screening method is carried out in media containing human AB type serum by contacting peripheral blood mononuclear cells (PBMC) with lipopolysaccharide (LPS; see pg. 4, lines 48-58 and pg. 6, paragraph 14). Preferred embodiments of the screening method involves contacting human PBMC with LPS in the presence or absence of the test compound, measurement of the suppressing action of the tested compound to induction of effector macrophages, and measuring the number of spontaneous plaque forming cells which would suggest effectiveness of the tested compound (see pg. 10, paragraphs 50-56). Ishibashi et al. further disclose that the method of screening a compound is characterized by the showing of less production of spontaneous plaque forming cell (SPFC) (see pg. 5, lines 11-13 and see test example 2). Importantly, Ishibashi et al. teach that the compounds tested can be used to treat glomerular lesions of the kidney (i.e. to treat renal glomerular lesions) and Langerhans islets lesions in the case of pancreas as well as chronic pigmentary skin diseases (i.e. which necessarily involved epidermal skin cells as skin cells are made of epithelial cells;

instant claims 40-41 and 44) by utilizing compositions containing tested compounds that suppress the induction of effector macrophages by contacting PBMC with LPS (see pg. 47, claim 9 and pg. 46, paragraphs 0306 and 0309). Ishibashi et al. further teach the promoting action of suppression of compound 4-2 is exemplified in table 2 where compound 4-2 was shown to reduce glomerular lesion cases by 50% (pg. 42, table 2, line 14).

Ishibashi et al. do not specifically teach a method of screening involving selecting a compound that increases the numbers of CD11b+ CD2+ macrophages and CD2- CD4+ T lymphocytes at a ratio not less than 20% compared with that measured in the absence of the test compound. Likewise, Ishibashi et al. do not teach the promotion of regenerating + CD2+ macrophages and CD2- CD4+ T lymphocytes in the screening method.

Because Ishibashi et al. teach the measurement of the suppressing action of a compound to be tested on the suppression of effector macrophages, Examiner concludes that one of ordinary skill in the art would have found it obvious to test CD11b+, CD2+ macrophages, CD2-, and CD4+ T lymphocytes since Ishibashi et al. teach that damaged renal tissue express tissue-specific immune cells depending upon the damaged area (see pg. 2, paragraph 0007). Consequently, CD11b+, CD2+ macrophages, CD2-, and CD4+ T lymphocytes would have been tested.

While Ishibashi et al. focus on the suppression of effector macrophages which caused renal damaged, Ishibashi did suggests that its tested compounds are not inhibitory to the macrophages involved in regeneration of the damaged tissue. Thus, one of ordinary skill in the art would have found obvious to test the macrophages involved in regeneration and test the promoting effects of its tested compounds on these macrophages as they are involved in the regeneration process of the damaged organ. Moreover, given that Ishibashi et al. teach the step of measuring the tested compound effectiveness in at least 50% suppression against plaque-induced lesions, one of ordinary skill would have found it obvious to screen for compounds that show a 50% effectiveness in the promotion of regenerating-promoting macrophages including CD11B+ CD2+ macrophages and regulatory CD2- CD4+ T lymphocytes.

Thus, to one of ordinary skill in the art at the time of the invention would have found it obvious to not only screen for tested compounds that suppress effector macrophages but also screen for compounds that are involved in promoting organ regeneration. Given the teachings of Ishibashi et al., one of ordinary skill would have been motivated to screen not only the tested compound for the suppressing activity of effector macrophages but also for the promoting activity of macrophages involved in tissue-regeneration which would necessarily involved CD11B+ CD2+ macrophages and regulatory CD2- CD4+ T lymphocytes with the reasonable expectation of providing an efficient method of screening for compounds that are effective in promoting macrophages such as CD11B+ CD2+ macrophages and regulatory CD2- CD4+ T lymphocytes involved in damaged tissue regeneration.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samira Jean-Louis whose telephone number is 571-270-3503. The examiner can normally be reached on 7:30-6 PM EST M-Th.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/S. J. L. /

Examiner, Art Unit 1617

08/31/2008

/SREENI PADMANABHAN/

Supervisory Patent Examiner, Art Unit 1617